

REMARKS

Claims 1-32 are pending in this application. Claims 1, 7, 13, 19, and 25 have been amended without prejudice or acquiescence in order to advance prosecution of the instant application. Applicants note that the amendment of “medicinal” to “pharmaceutical” in claims 1 and 7 is tangential. Support for the claim amendments may be found on page 13, line 10, and on page 16, lines 10-15. The issues outstanding in the instant application are as follows:

- Claims 1-32 have been rejected under 35 U.S.C. § 112 second paragraph, as allegedly being failing to define the subject matter regarded as the invention.
- Claims 13, 14, 18, 19, 20, 25-28, and 32 have been rejected under 35 U.S.C. § 102(b)/103(a) as allegedly being anticipated by and/or obvious over CN 1210695.
- Claims 1-20, and 25-32 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over RO 87637 in view of CN 1210695 and Remington’s.

I. 35 U.S.C. § 112 issues

The Examiner has rejected claims 1-32 as failing to set forth the subject matter regarded as the invention. Applicants respectfully traverse.

Claims 1-32 distinctly point out the subject matter that Applicants regard as their invention. Applicants have amended claims without prejudice or acquiescence in order to advance prosecution of the instant application. Support for the amendments may be found in the specification on page 16, lines 10-15. Applicants respectfully request withdrawal of the 35 U.S.C. 112 rejection.

II. 35 U.S.C. § 102(b)/103(a) issues

The Examiner has rejected claims 13, 14, 18, 19, 20, 25-28, and 32 under 35 U.S.C. § 102(b)/103(a) as allegedly being anticipated by and/or obvious over CN 1210695. Applicants respectfully traverse.

"A claim is anticipated only if **each and every element** as set forth in the claim is found either expressly or is inherently described in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987) (emphasis added). "The identical invention **must be shown** in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) (emphasis added). "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "

CN 1210695 teaches drinking water with calcium glutarate in concentrations of 10-1,000mg/L. Applicants teach a method of inhibiting phosphorous absorption in the gastrointestinal tract by administration of an effective amount of a calcium glutarate composition in a single dose form, said composition excluding non-glutarate calcium salts in amounts sufficient to neutralize gastric acidity. Applicants also teach single dose compositions and compounds of calcium glutarate sufficient to bind with phosphorous in the gastrointestinal tract.

CN 1210695 teaches drinking water supplemented with calcium salts for nutritional value. CN 1210695 does not teach or suggest a method of inhibiting phosphorous absorption in the gastrointestinal tract. CN 1210695 does not teach or suggest compositions excluding non-glutarate calcium salts in amounts sufficient to neutralize gastric acidity. CN 1210695 does not teach or suggest single dose compositions. Thus, CN 1210695 does not teach or suggest all the limitations of claim 13 and there is no anticipation of claims directed towards compositions for or methods of inhibiting gastrointestinal absorption of phosphorous as taught by Applicants.

"While the claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allow. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification." *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) Applicants assert that the term "single dose" is well known to one skilled in the art, and thus must be given its plain meaning. As defined in Dorland's Illustrated Medical Dictionary, a

dose is “a quantity to be administered at one time.” Thus, Applicants maintain that one with skill in the art would understand that a single dose is intended to be administered at one time.

As such, drinking water formulations comprising calcium salts taught by the CN 1210695 are nonequivalent to a pharmaceutical composition which comprises a single dose of calcium glutarate. For the reasons above, a single dose of the pharmaceutical composition is known to one with skill in the art to be intended for consumption at one time. Drinking water as taught by CN 1210695 that is enriched by calcium salts has no limitations indicating that consumption of any particular serving, or dose, is required. There is simply no teaching in CN 1210695 of what consumption levels of drinking water are required. Also, not only are levels of consumption not described, there is no teaching of single dose consumption of any amount of the calcium salt-enriched drinking water. Thus, there is no inherent anticipation of the claimed invention, as the doses taught by applicants to be consumed in a single dose are not necessarily present in CN 1210695. Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency. See *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). Inherent anticipation requires that the missing descriptive material is “necessarily present,” not merely probably or possibly present, in the prior art. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Inherency does not embrace probabilities or possibilities. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999).

As CN 1210695 does not teach or suggest all the limitations of the claimed invention, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(b)/103(a) rejection.

III. 35 U.S.C. § 102/103 issues

The Examiner has rejected claims 1-20, and 25-32, under 35 U.S.C. § 103(a) as allegedly being obvious over RO 87637 in view of CN 1210695 and Remington’s. Applicants respectfully traverse.

“To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

RO 87637A teaches medicinal composition containing multiple calcium salts, including calcium glutarate, calcium lactate, and calcium carbonate (CaCO_3). Remington's teaches methods of preparing pharmaceutical dosage forms, and CN 1210695 teaches calcium glutarate mineralized drinking water.

Applicants teach a method of orally administering to a person in need thereof a quantity of a composition of calcium glutarate sufficient to bind with phosphorous in the gastrointestinal tract and inhibit phosphorous absorption. Applicants teach calcium glutarate compositions excluding non-glutarate calcium salts in amounts sufficient to neutralize gastric acidity. Applicants also teach single dose compositions and compounds of calcium glutarate sufficient to bind with phosphorous in the gastrointestinal tract. The combined references do not teach a method of orally administering to a person in need thereof a quantity of a medicinal composition of calcium glutarate sufficient to bind with phosphorous in the gastrointestinal tract and inhibit phosphorous absorption. The combined references do not teach single dose compositions and compounds of calcium glutarate sufficient to bind with phosphorous in the gastrointestinal tract. The Examiner is directed to the arguments above in which it is established that single dose compositions are known to one with skill in the art to be administered at one time. The combined references do not teach calcium glutarate compositions excluding non-glutarate calcium salts in amounts sufficient to neutralize gastric acidity. The combined references do not teach calcium glutarate compositions excluding non-glutarate calcium salts in amounts sufficient to neutralize gastric acidity.

Applicants respectfully reiterate that a claim is considered obvious only if the claimed invention as a whole would have been obvious to a skilled artisan. *In re Mayne*, 104 F.3d 1339, 1342 (Fed. Cir. 1997). "It is insufficient to establish obviousness that the separate elements of the invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the elements." *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957 (Fed. Cir. 1997). When relying on a modification of the prior art to reject a claim, it is incumbent upon the Examiner to identify some suggestion in the prior art to make the modification. *In re Mayne*, 104 F.3d at 1342. An invention is not obvious just because it is "obvious to try," such that the prior art gives "only general guidance as to the particular form of the invention or how to achieve it." *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988). This is particularly true since it is well established that "there is usually an element of 'obviousness to try' in any research endeavor." *In re Tomlinson, Hall, and Geigle*, 150 USPQ

623, 626 (CCPA 1966) Applicants assert that the Examiner is improperly relying on an "obvious to try" standard for establishing obviousness. When the prior art only provides general guidelines concerning the state of the art, but no suggestion to modify the art to provide the claimed invention, there can be no finding of obviousness. As Remington's only provides general information regarding the state of pharmaceutical preparations, it does not provide a motivation to combine the cited references. Similarly, RO 87637 and CN 1210695 also provide no suggestion for the combination.


Thus, as the combination of the references do not teach all limitations of the claimed invention, and there is no motivation to combine the references, claims 1-20, and 25-32 are nonobvious. In light of the above arguments, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

A check in the amount of \$440.00 is attached to cover the RCE filing fee and a one-month extension of time. Applicant believes no additional fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02490US0 from which the undersigned is authorized to draw.

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Respectfully submitted,

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